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# MAN AND BIOTECHNOLOGY

## Report of the Ethics Committee

*Royal Norwegian Ministry of Health and Social Affairs*

**1991**

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# Introduction and Summary

The Ethics Committee was appointed by Royal Decree of 8 April 1988 for the purpose of drawing up ethical guidelines to cover the aspects of research and development in biotechnology and gene technology relating to human beings. The background for this appointment was the Storting's request, in connection with its debate on the bill relating to artificial procreation in June 1987, for a Report to the Storting (the national assembly) on biotechnology and gene technology. This Report was to provide a basis for ethical debate and proposals for future legislation. The present report by the Ethics Committee will form the basis of the Report to the Storting. The Ethics Committee was chaired by Professor Julie Skjæraasen of Rikshospitalet, the National Hospital, Oslo.

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## SURVEY OF THE CONTENTS OF THE REPORT

### Chapter 2

Chapter 2 describes the appointment, mandate, composition and working procedures of the Committee. The chapter also provides a summary of the work done by previous governments on biotechnology and of the intentions of the present government in this regard. This includes the Committee's memorandum to the Minister of Health and Social Affairs in early 1989 concerning a provisional assessment of the need for continual follow-up of developments in biotechnology and gene technology, and describing the official board on biotechnology and gene technology that is being set up in accordance with a decision by the Storting in June 1989.

### Chapter 3

Chapter 3 starts with the Committee's definition of its mandate. The Committee decided to concentrate on areas of biotechnology and gene technology that have been especially debated in Norway and many other countries and in international bodies, because they are new and/or because of their potential for raising ethical questions.

The rapid development of methods based on biotechnology and gene technology for application to humans has been accompanied by an information explosion across national and research boundaries. Scientists in many different countries are working on the same or similar problems at the same time, and continually supply each other with new premises for further work. The same questions are being discussed in many different international agencies, and the international debate has caused many countries, inside and outside Europe, are preparing national guidelines and legislation that reflect both the international debate and their own ideological and political values and norms.

The speed of developments in this field makes it impossible to remain completely up to date. This may result on the one hand in unfounded fears based on imagined threats, and on the other in an inability to promote serviceable legislation and disposition of resources due to lack of knowledge. The Committee therefore considers it imperative to increase the level of understanding among the general population. To this end, the Committee has chosen to concentrate on relatively comprehensive descriptions of the issues and methods of biotechnology and gene technology within the areas included in the mandate, rather than on discussions of abstract ethical models and theories. The ethical judgments of the Committee are naturally influenced by the personal opinions of its members, which gradually evolved during the long deliberations entailed in preparing the report. The ways in which methods of biotechnology and gene technology are regulated will have consequences for both individuals and society as a whole. The Committee considers it important that relevant ethical questions related to biotechnology and gene technology are discussed by the public at large, and has therefore done its best to present complex subjects as simply and understandably as possible. It would be unethical to take up hard and fast positions on the basis of uninformed views.

The answers to many of the questions discussed in this report will depend on individual values. In the Committee's opinion many of these questions do not have «right" or «wrong" answers and therefore the report does not always present unanimous conclusions. Ideally, the development and application of research on biotechnology and gene technology would be directed towards common objectives based on norms and values that are widely accepted among the Norwegian population. In practice, however, the norms and values are themselves influenced by developments in society.

Chapter 3 also provides a survey of the relevant concepts and methods in gene technology, explaining relevant terms like cells, DNA, genes and chromosomes. The chapter provides an overview of present and future techniques in gene technology, and of genetic diseases, including the different forms of Mendelian heredity. A few genetic diseases or conditions where modern gene technology can provide medical benefits in the form of more precise diagnoses, but where these very benefits can create ethical problems, are also reviewed.

The number of diseases known to be due to Mendelian heredity is growing as our knowledge of the connection between heredity and disease increases. Up to 1990, 4930 Mendelian diseases have been described. Most of these are extremely rare, and in many cases only one or a few cases have been registered worldwide. It is predicted that at least 1 per cent of a given population will suffer from a Mendelian disease which is either congenital, i.e. present at birth, or appears at some time in the course of their lives. We do not know with certainty how many people in Norway suffer from a Mendelian disease, nor do we know exactly how many of the almost 5000 such diseases are represented in Norway. In the case of certain rare diseases, there cannot be more than one or at most a few cases in this country.

A list of current projects concerned with mapping human genes, with comments on the potential ethical problems associated with such mapping, is given at the end of chapter 3.

**Chapter 4**

Part of the Committee's mandate was to examine the ethical principles and values current in Norwegian society that would form a suitable basis for ethical guidelines for biotechnological research and development. The Committee defines ethical guidelines as a set of moral principles that are not legally binding but that propose recommended courses of action in particular situations. The population should in general be able to agree on these principles, irrespective of their religious or political beliefs. In the Committee's opinion, ethical principles based on both Christian and humanistic ideals would be acceptable to the Norwegian population as a whole. The chapter contains a survey of ethical concepts and traditions, pointing out the diversity of theories and the fact that there are often considerable differences of opinion prevailing among moral philosophers and other thinkers with backgrounds in ethics. Brief outlines are given of present-day Christian and humanistic ethics.

In spite of the fact that ethical principles may be based on either religious or secular philosophies of life, there is often more agreement than disagreement on guiding principles and specific choices. The whole of Western culture, including Norway, has a common ethical tradition based on a respect for life and human dignity. Comparisons of Christian and humanistic ethics show that differences between them on specific points are often concerned more with reasons than with results. In spite of this, the points raised in this report will lead to different conclusions depending on whether they are judged according to teleological or deontological ethical principles and depending on views on self-determination.

**Chapter 5**

This chapter contains a survey of Norwegian and Nordic committees, reports, etc. concerned with biotechnology and gene technology.

**Chapter 6**

Chapter 6 contains an overview of national and European legislation, recommendations, etc. on biotechnology and gene technology. Many countries both in and outside Europe are engaged in preparing national guidelines and legislation for regulating reproduction and gene technology, but there are great differences between countries as regards their proposed and established legislation, both in Europe and between the Nordic countries. However, a desire for coordination on a Nordic and a European basis has been expressed in the Nordic Council and the Council of Europe, respectively.

**Chapter 7**

Part of the Committee's mandate is to discuss ethical questions raised by research and development in biotechnology and gene technology in the foreseeable future. Because of the enormous speed in the progress of research, and in the spread of these methods as applied to human beings, the Committee chose to base its discussions on developments in techniques, methods, types of treatment, etc. that reputable experts in the field regard as probable. They also chose to define the foreseeable future as about six to eight years after the report has been completed and debated in the Storting, and the subsequent legislation and guidelines have been laid down.

**Chapter 8**

In this chapter the Committee discusses the use of screening in relation to genetic disease. The Committee has in principle a critical attitude to the use of screening to register the prevalence of a genetic disease, individual predispositions towards a genetic disease or the presence in an individual's genetic constitution of a genetic disease. The members of the Committee do not agree on how far a sceptical attitude towards genetic screening should be expressed.

## Chapter 9

This chapter contains a discussion on reproduction technology. During the 12 years that have passed since the first birth following in vitro fertilization, artificial procreation has become practised all over the world. At least 35,000 children are thought to have been born as a result of such treatment. The number is so large that there is no international overview. The Nordic countries have one of the highest success rates in the world in this respect.

In vitro fertilization (IVF) was discussed in detail in Norway during the debate on the proposed bill relating to artificial procreation in 1987. In the report the Committee discusses the ethical problems raised during the debate and later by the practice of the method. These include the question of a continued statutory prohibition against research on fertilized eggs, indications for IVF, changes in the time limit for keeping frozen fertilized eggs, egg donation and selective reduction of fetuses.

The majority of the Committee consider that IVF should continue to be allowed in Norway. Although the method is open to ethical objections, the majority regard its value in the treatment of childlessness as being overwhelmingly positive, and emphasize the fact that it is already widely accepted in Norwegian society. A minority of one considers that IVF should be prohibited in Norway because it is based on research that this member finds ethically unacceptable and because it provides considerable opportunities for manipulation in combination with other techniques.

According to the present Act, fertilization outside the body may only be carried out in the case of infertility in the woman. On the basis of developments occurring since the Act entered into force in 1987, the Committee proposes that the Act be changed to allow access to IVF treatment for infertility in men as well as women and in the case of unexplained infertility.

The present Act provides that fertilization outside the body may only be carried out with the eggs and sperm of the couple involved. This means that at present the use of donor sperm for IVF is prohibited. A minority of the Committee wishes to amend the Act so as to allow the use of donor sperm in connection with IVF.

According to the present Act, fertilized eggs may only be implanted in the woman from whom they came, which means that donation of eggs is prohibited. The majority of the Committee wish to retain this prohibition. A minority proposes that donation of eggs should be permitted on medical indications. This minority proposes that the statutory provisions ensuring the anonymity of sperm donors should then be extended to apply to egg donation. Permission to donate eggs would also involve an amendment to the Children Act defining the child's mother.

Existing legislation prohibits research on fertilized eggs, but the scope of this prohibition is unclear. The term «research on fertilized eggs" is unclear and may have different meanings in different contexts. The Committee recommends retaining the wording of the prohibition, but with a more precise definition of the term «research». The Committee considers that the extraction and fertilization of eggs exclusively for research purposes should be prohibited. On the other hand, if eggs are extracted and fertilized for the purpose of returning them to the woman's uterus, then changing the procedure for treating the eggs in order to improve the method should, in the Committee's opinion, be permitted. The Committee considers that eggs that are not selected for implantation must be destroyed or frozen for later implantation, and that any other use of superfluous eggs should be prohibited. In order to reduce the number of multiple pregnancies, the seven Norwegian IVF clinics have established a common practice since 1 January 1990 of implanting no more than three fertilized eggs at each treatment. The Committee considers that this practice should be made obligatory and laid down in the form of regulations.

Experience has shown that the freezing of fertilized eggs is a significant contribution to the success of IVF. Centres all over the world are using this method to an increasing extent. The most recent statistics show no indication that freezing and thawing of fertilized eggs lead to a higher incidence of malformations. According to present legislation, frozen fertilized eggs may not be stored for more than 12 months. A majority of the Committee recommend an extension of this time to three years, to ensure that there is a real possibility of achieving a second pregnancy. A minority considers that the storage limit should be reduced to nine months in order to exclude the possibility of a second pregnancy.

Selective reduction of fetuses means that the number of fetuses in the uterus is reduced by ensuring that one or more die in order that the remainder may continue to develop. This procedure is applicable in theory to natural multiple pregnancies as well as IVF-induced pregnancies. The Committee considers that selective reduction of fetuses should not be permitted in such cases. The present Act relating to the termination of pregnancy contains no provisions dealing with this question.

**Chapter 10**

In this chapter the Committee continues to expand its views on the prohibition of research on fertilized eggs, and discusses questions raised by research on fetuses and by the use of fetal tissues and organs for purposes of transplantation. The Committee's recommendation to retain the prohibition on research on fertilized eggs entails that fertilizing eggs for research purposes would also continue to be prohibited. On the other hand, the Committee acknowledges that information and methods based on research on fertilized eggs can lead to significant improvements in IVF treatment, and that this treatment is nowadays regarded as a benefit to which people are entitled and which is expected of a modern health service. The Committee is aware that prohibiting research on fertilized eggs and accepting the methods based to some extent on such research can be said to be inconsistent, and even unethical. However, the Committee does not consider that any circumstances have arisen within the last three years to justify the introduction of research on fertilized eggs in Norway. The Committee therefore feels that Norwegian society will simply have to live with this inconsistency.

In the Committee's view research using material from spontaneously aborted fetuses should be permitted after evaluation by a regional research ethics committee. Research based on experiments carried out on fetuses before an induced abortion should in the Committee's view be prohibited. A majority of the Committee consider that cells and tissues from aborted fetuses should continue to be used in the diagnosis of virus diseases in approved medical laboratories as is done today, whereas a minority considers that such use of cells and tissues from aborted fetuses is ethically questionable. The majority consider that the Ministry of Health and Social Affairs should decide on the future use of fetal tissue for transplantation purposes, while the minority considers the transplantation of fetal tissue from an induced abortion to be ethically unacceptable.

**Chapter 11**

The Committee uses the term «prenatal diagnostics" to refer to all forms of examination of the fetus to diagnose or exclude the presence of disease or malformation before birth. It has focussed especially on ethical questions raised by amniocentesis and chorion biopsies, ultrasound diagnosis of abnormal fetal development and possible future methods of gene technology applicable at an early stage of pregnancy.

Research groups in many parts of the world are now working on methods for testing the mother's blood in early pregnancy. The Committee's view is that such tests are at present in the experimental stage and may not become applicable within the foreseeable future. If they should become practicable, the Committee considers that they should be subjected to the same criteria as other forms of prenatal diagnosis.

Preimplantation diagnostics refers to the testing of a fertilized egg to find out whether it is the carrier of a genetic disease. Such testing has to be done in connection with IVF, before the egg is implanted in the uterus. The Committee considers that the available international findings are at present too inconclusive to be able to judge whether such diagnostic methods should or should not be permitted, and that in any case, such a method should only be used in cases where there is a high risk of a serious genetic disease. A minority does not consider that any form of preimplantation technique for diagnosing fertilized eggs with genetic defects should be permitted.

The Committee considers that ultrasound examinations can give rise to an ethical dilemma. On the one hand this method allows a better monitoring of pregnancy, with the possibility of preventing injury to the fetus and of diagnosing serious developmental defects. On the other hand, the way this method is practised today contains an element of population screening which is ethically questionable. The pregnant woman and her partner may be faced with an ethical dilemma that they lack the knowledge and experience to solve. When routine examinations of pregnant women were introduced in Norway, these problems were only foreseen to a very limited extent. In the Committee's view the question of ultrasound examinations for all pregnant women should have been put to the Storting.

Within the next few years, it is thought that a technique using a combination of tests of the mother's blood will be able to reveal 60 per cent of fetuses with Down Syndrome in the 16th week of pregnancy. If this is combined with ultrasound examinations, an even greater proportion of fetuses with Down Syndrome will be able to be diagnosed. These new techniques raise so many ethical questions that the Committee decided to deal with Down Syndrome separately.

A majority of the Committee consider that the use of this particular test for identifying Down Syndrome in utero should be prohibited for women who are not at risk. A minority considers that since the test has a low standard of reliability, such a prohibition is unnecessary.

A majority of the Committee consider that a diagnosis of Down Syndrome in utero should constitute valid grounds for an abortion at the parents' request, but that this does not imply any denigration of the human worth of a fetus with the diagnosis of Down Syndrome. These members consider that in certain cases this condition can represent an intolerable burden for the family as a whole. The minority feels that the diagnosis Down Syndrome does not in itself consitute a reason for terminating a pregnancy, and propose an amendment of the Act relating to the termination of pregnancy providing that non-fatal developmental abnormalities are not in themselves an indication for abortion.

The Committee has differing views on what constitute acceptable indications for selective abortion. The majority do not consider that there is any reason to propose changes in the existing practice, but recommends that neither Turner Syndrome nor Klinefelter Syndrome should in themselves be considered indications for abortion. The minority considers that abortion is only acceptable in cases where there is a risk that the child itself will have to live with a great deal of pain and suffering.

The Committee also has differing views on the question of maternal age as an indication. Three members propose that there should be no change in the existing practice of offering amniocentesis to all women who become pregnant over the age of 38. Three members consider that the age limit should be lowered to 35. Two members consider that age should not be an indication at all, so that women over the age of 38 would no longer be offered the possibility of prenatal diagnosis on the basis of their age alone.

The Committee proposes an amendment to the Act relating to medical practitioners to ensure that the parents are not informed of the sex of a baby until after the 12th week of pregnancy, except in cases of serious sex-related diseases. In the opinion of the Committee, selective abortion based on prenatal genetic tests in the case of multiple pregnancy should be evaluated according to the same criteria as in the case of a single fetus.

The question of abortion on demand is outside the Committee's mandate, and the provisions of the Act relating to the termination of pregnancy were therefore not discussed in a general way except in relation to prenatal diagnosis. However, the Committee is clearly aware that a future increase in techniques for diagnosing genetic diseases and chromosomal errors before the 12th week of pregnancy may lead to a fresh debate on the right to abortion on demand, based on different premises. A minority of the Committee proposes an amendment to the Act relating to the termination of pregnancy providing that the termination must be carried out before the end of the 10th week of pregnancy.

### Chapter 12

In this chapter the Committee points out that since the Act relating to transplantation and the regulations defining the moment of death do not seem to have caused any ethical conflicts in Norway, it did not seem necessary to discuss fundamental ethical problems associated with organ transplantation. The Committee recommends that the need for formal guidance of physicians who have to decide on the donation of organs from dead bodies be evaluated, and likewise the necessity for an information campaign about the need for organs for transplantation. The Committee proposes that the Act relating to transplantation be amended to include a prohibition on the buying and selling of organs.

### Chapter 13

The new techniques for investigating DNA allow information to be obtained about an individual's genes, and this raises considerations about the individual's right to privacy. In the next four chapters the Committee discusses the use of DNA technology for medical purposes in four different contexts: the testing of employees, the diagnosis of carriers of genetic disease, predictive testing of persons with a high risk of developing a particular genetic disease, and testing to reveal any genetic predisposition towards certain common diseases. Chapter 13 deals with questions that concern the right of privacy, which are similar in all medical contexts, with the need to regulate the use of DNA techniques and with the confidential treatment of the findings. In the opinion of the Committee genetic testing of employees at their place of work should be prohibited, and in cases where tests are carried out, it should be prohibited to reveal the results to present or future employers.

The Committee has to some extent divided views on the regulations required to govern the use of DNA technology. The Committee agrees that an institution intending to use such techniques must have specific approval from the Ministry of Health and Social Affairs. The institution must deliver written reports to the Ministry on all applications of such techniques involving human beings both before and after birth. Four of the Committee members consider that the use of DNA technology should be based on expert medical opinion, and that the Ministry of Health and Social Affairs should only be authorized to monitor such activities on the basis of written reports, and to interfere if necessary. The other four members consider that for the time being the Ministry of Health and Social Affairs should be authorized to approve the use of DNA diagnostic techniques in the cases of specific diseases for which these tests are applicable. The entire Committee agrees that DNA techniques should only be applied in prenatal diagnosis to test for serious genetic diseases.

The regulation of the use of DNA techniques for diagnostic, preventive or other special purposes, and the prohibition on the use of information concerning an individual's genes should in the view of the Committee be incorporated into an act regulating the use of gene technology. The prohibition against the use of genetic information should apply to the authorities, present and future employers, educational institutions, medical institutions, pension funds, life insurance companies and other institutions requiring medical data. It should be prohibited to request, possess, receive or make use of such information as well as to attempt to find out whether such tests have been carried out.

**Chapter 14**

Cystic fibrosis (CF) is the only serious recessive genetic disease that is so common in Norway that there is some point in discussing the screening of the whole population or certain groups for carriers of the disease. The factor that makes diagnosing the carriers of this disease so relevant is that the same genetic defect has been identified in 70-80 per cent of carriers in many different ethnic groups. The Committee therefore decided to consider this disease separately. There are about 185 persons with CF in Norway, of whom about 50 are over 18 years of age. Previously most children with CF died before reaching school age, but today the life expectancy of such individuals is steadily improving. About 150,000 people in Norway are healthy carriers of the CF gene. In the opinion of the Committee a general testing of the population to establish carriers of the CF gene should not be introduced.

**Chapter 15**

There are a number of rare Mendelian diseases that only become manifest later in life. In some cases DNA technology has made it possible to diagnose the disease before it actually appears. The ethical and legal problems arising from the use of DNA techniques for predictive testing have been debated in many countries in recent years. An especially relevant disease in this context is Huntington's disease. Chapter 15 describes this serious, inexorably progressive disease, which attacks the nervous system. Huntington's disease is a predominantly inherited disorder, and certain families in Norway have a high incidence. About 160 persons in Norway are known to have the disease. A number of countries have introduced predictive testing, and in early 1990 the Ministry of Health and Social Affairs gave permission for predictive testing to be carried out on adults at risk at their request (i.e. persons with a 25 or 50 per cent risk of having inherited the disease). A comprehensive set of ethical and practical guidelines has been drawn up, and is presented in an annex to the report.

**Chapter 16**

Genetic factors contribute to a predisposition or resistance towards many of the most widespread diseases in Norway today. In chapter 16 the Committee discusses the use of DNA techniques to reveal the risk of disease, i.e. investigations of the genetic constitution of healthy people to evaluate whether they are likely to suffer from a particular disease in the future. By no means all of those predisposed to a disease will develop it. At present DNA techniques to demonstrate a predisposition to a genetic disease are not in use in Norway. The Committee considers that the use of DNA techniques to reveal a genetic disposition towards a disease should be limited to cases with a specific medical objective, and where the efficiency of the DNA technique in identifying persons at risk has been documented. The Committee recommends that such DNA techniques should not be used to test large population groups for their predisposition to a particular disease until there is adequate evidence of the efficiency of preventive measures, and until considerations connected with the right of privacy have been taken care of. The use of DNA techniques on medical indications in connection with familial disease should be permitted.

**Chapter 17**

There is no effective treatment for the majority of genetic diseases. The possibility of correcting genetic errors by gene therapy has therefore been discussed in international fora for several years. The first experiments with such therapy have been started in the USA. There are two kinds of therapy - somatic gene therapy, which only cures the person being treated, and germ cell therapy, where the altered genetic material is passed on to future generations. If somatic gene therapy proves to be an effective form of treatment for certain genetic diseases, it should, in the Committee's opinion, be permitted in Norway. However, the Committee considers that even if germ cell therapy should become practicable without undesirable side effects, it should not be permitted. Germ cell therapy should be rejected on ideological grounds, because of the risk of man-mediated changes in the human species.

### Chapter 18

When considering the question of the transfer of genes between humans and animals, a line should be drawn between the transfer of single genes from humans to animals and cross-fertilization between humans and other species for the purpose of creating a creature that is half human and half animal. The latter is biologically impossible.

### Chapter 19

There is a widespread belief among organizations representing the disabled that gene technology will have consequences far beyond the sphere of medicine itself. Many believe that the most significant of these will have a general moral and social character. In chapter 19 the Committee emphasizes that the living conditions for the disabled will influence future attitudes in our society towards gene technology. The Committee is of the opinion that ensuring that the disabled live under conditions encouraging equal status and the greatest possible participation in all areas of society will call for continuous and long-lasting efforts.

### Chapters 20 and 21

Chapter 20 contains a discussion on legal, economic and administrative measures for direction and control of biotechnological developments based on the Committee's proposals in previous chapters.

Chapter 21 discusses the need for expertise among administrative officers, the assignment of responsibility for genetic counselling and the need for a report on the resources available for carrying out DNA diagnosis in individuals after birth.